

February 7, 2005

Mr. Randall V. Brumbaugh
Attorney At Law
417 W. Foothill Blvd.,
PMB B-175
Glendora, CA 91741

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION ON AMENDMENT REQUEST
FOR EXEMPT DISTRIBUTION LICENSE AND SEALED SOURCE AND DEVICE
REGISTRATION CERTIFICATE

Dear Mr. Brumbaugh:

I am responding to your letter dated January 25, 2005. Your letter requested the amendment of Unertl Optical Company, Inc.'s (Unertl) sealed source and device registration certificate (NR-1200-D-101-E) and exempt distribution license (No. 27-23901-01E) regarding three separate issues. The Nuclear Regulatory Commission's (NRC) responses to your questions are stated below.

1. Unertl requested confirmation that it may insert tritium into original equipment gun manufacturers' gun sights. In order to confirm this request, Unertl will need to provide the following information:

- 1.1 Confirm that Unertl will only use those configurations of tritium that it has already been approved for on its sealed source and device registration certificate and its exempt distribution license. Please also confirm that the gun sights will not surpass the maximum activity stated in the registration certificate.
- 1.2 State the location where the original gun manufacturers' sights or a gun sight manufacturers sights will be drilled. In addition please provide assurance that the holes will be checked for design conformity to the dimensions stated in Unertl's registration certificate.
- 1.3 Please provide a table that compares Unertl's currently approved materials for gun sights with those using sights manufactured by the original gun manufacturer or other gun sight manufacturers. Please provide the material data sheets such as the material data sheet for the metal injection molding (MIM) and other potential material. Please describe what minimum qualifications Unertl will require and verify for such gun sights prior to the inclusion of tritium.
- 1.4 Describe the label and licensing number information that will be placed on the original gun manufacturers' sights or other sight manufacturers' gun sights Unertl plans to distribute.

- 1.5 Please provide assurance that Unertl will only distribute completed and finished original gun manufacturer gun sights or other sight manufacturers' gun sights, and that the gun sights will not be altered following distribution to gun or sight manufacturers.
- 1.6 Provide an analysis on prototype testing for the units that require using the sights manufactured by the original gun manufacturer and on sight manufacturers' sights. The NRC's "Consolidated Guidance About Materials Licenses: Application for Sealed Source and Device Evaluation and Registration," NUREG-1556, Vol. 3, Rev.1, states that "[applicants need to determine an appropriate method to demonstrate the products ability to maintain its integrity when subjected to conditions or normal use and likely accidental conditions." This may include testing a prototype of the product, performing an engineering analysis, operational history of the product, or comparison to a similar or equivalent Unertl model previously reviewed and registered.

2. Unertl requested to amend its sealed source and device registration certificate and exempt distribution license for approval of inserting tritium vials into blocks or cylinders of metal for inclusion into emergency personnel equipment, tools, hunting and fishing equipment and sporting equipment for distribution. Unertl's current sealed source and device registration certificate is for the manufacturing of luminous gun sights.

NRC regulations stated in 10 CFR 30.15, provide a list of certain items that have been approved for persons to incorporate tritium. These items include watches, lock illuminators, balances of precision, automobile shift quadrant, marine compasses, thermostat dials and pointers, and electron tubes. The items must meet certain requirements that are stated in 10 CFR 30.15. These items are also required to meet the requirements set by 10 CFR 32.14.

According to 10 CFR 32.22, an application for a specific license to manufacture, process, or produce self-luminous products or to initially transfer such products to persons exempt from licensing requirements for use pursuant to 10 CFR 30.19 may be submitted. Items that have been approved in the past include gun sights, watches, and a flashlight. According to 10 CFR 30.19 (c) the exemption does not apply to tritium, krypton-85, or promethium-147 used primarily for frivolous purposes in toys or adornments. In addition under 10 CFR 32.22(b) the Commission may deny an application if the end use of the product cannot be reasonably foreseen. Any new products that would contain tritium must be approved by the Commission.

The broad authority that Unertl has requested is not acceptable. Any application would have to be very specific and would have to meet the requirements listed in 10 CFR 32.22, and would also have to meet the Commission's requirement that the tritium is not used for frivolous purposes such as in toys or adornments. In addition, the product must be finished prior to initial distribution, the finished product would have the tritium sources already installed prior to initial distribution from Unertl. The NRC would need to perform a safety evaluation on the finished product as a whole, and determine that it would contain an unusual degree of utility and safety of a product that was subject to mishandling. The end use of a product has to be clearly defined and demonstrate that it would be a benefit that will accrue to or be denied the public

because of the approval or disapproval of the product. NRC has historically not handled broad requests for exempt products through the sealed source and device and exempt distribution licensing process. These are typically evaluated as part of a rulemaking which includes stakeholder participation.

The regulations do allow for applicants to submit a sealed source and device application that requests to have a model registered as a series on their registration certificate. In order to have a model listed as a series, there should be similarities in the design and construction of the products. The items that Unertl has requested to be added are not similar enough to the gun sights, previously reviewed and approved, to amend them to your current registration certificate. Therefore, Unertl would need to apply for a new sealed source and device certificate for groups of similar products.

Alternatively, an applicant may petition for rulemaking to amend NRC's regulations. The regulations for a petition for rulemaking are found in 10 CFR 2.802.

3. Unertl requested to develop a source supplier for tritium vials other than the that which has already been approved by the NRC.

The using of a source from any new source supplier to Unertl will require an amendment to the sealed source and device registration as well as to the exempt distribution license.

Unertl will have to provide the following information similar to a new application in order to approve a different source for inclusion into gun sights:

- Designation of the new supplier;
- Description of the sights with the new source, such as the model number, dimensions, materials used, and activity per source;
- Installation of the sources in the sights as well as the process of how the tritium vials will be affixed to the gun sights;
- Evidence that the new sources to be used, once installed in the UNSF-A and the UNSR-A through J, will maintain their integrity when subjected to normal use and likely accident conditions. In providing this information, you may use any of the methods listed in Section 10.5, Prototype Testing, NUREG-1556, Vol. 3, Rev. 1; i.e., actual history of the product, engineering analysis, operational history, or comparison to similar or equivalent models.

It is important to realize NRC's sealed source and device registration certificate does not allow for distribution. Unertl's exempt distribution license, number 27-23901-01E is the document that allows for distribution. In that document the only gun sights that are currently allowed to be distributed to persons exempt from licensing are the models UNSF-A, and UNSR-A through UNSR-J.

If you have any questions, please contact me at (301) 415-6613 or Mr. Tomas Herrera of my staff at 301-415-7138.

Sincerely,

/RA/

Timothy E. Harris, Section Chief
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

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Timothy E. Harris, Section Chief
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Distribution:
IMNS r/f

ML050390234

*see previous concurrence

OFFICE	MSIB	MSIB	MSIB
NAME	THerrera*	JJankovich*	THarris
DATE	2/1/05	2/1/05	2/7/05